

examination on matters outside the scope of direct examination shall be conducted in the manner of direct examination and may proceed by leading questions only if the witness is a hostile witness, an adverse party, or a witness identified with an adverse party.

(f) Upon motion of any party, the presiding officer may order witnesses excluded so that they cannot hear the testimony of the other witnesses. This rule does not authorize exclusion of:

- (1) A party who is an individual;
- (2) In the case of a party that is not an individual, an officer or employee of the party designated to be the party's sole representative for purposes of the hearing; or
- (3) An individual whose presence is shown by a party to be essential to the presentation of its case, including an individual employed by a party engaged in assisting counsel for the party.

(g) If a witness' testimony is submitted in writing prior to cross-examination, the cross-examining party need not subpoena the witness or pay for his or her travel to the hearing. The sponsoring party is responsible for producing the witness at its own expense, and failure to do so shall result in the striking of the witness' testimony.

§ 17.39 Evidence.

(a) The presiding officer shall determine the admissibility of evidence.

(b) Except as provided in this part, the presiding officer shall not be bound by the "Federal Rules of Evidence." However, the presiding officer may apply the "Federal Rules of Evidence" when appropriate, e.g., to exclude unreliable evidence.

(c) The presiding officer shall exclude evidence that is not relevant or material.

(d) Relevant evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Relevant evidence may be excluded if it is privileged under Federal law.

(f) Evidence of furnishing or offering or promising to furnish, or accepting or

offering or promising to accept, a valuable consideration in settling or attempting to settle a civil money penalty assessment which was disputed as to either validity or amount, is not admissible to prove liability for or invalidity of the civil money penalty or its amount. Evidence of conduct or statements made in settlement negotiations is likewise not admissible. This rule does not require the exclusion of any evidence otherwise discoverable merely because it is presented in the course of settlement negotiations. This rule also does not require exclusion when the evidence is offered for another purpose, such as proving bias or prejudice of a witness or opposing a contention of undue delay.

(g) The presiding officer may in his or her discretion permit the parties to introduce rebuttal witnesses and evidence.

(h) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the presiding officer pursuant to § 17.28.

§ 17.41 The administrative record.

(a) The hearing will be recorded and transcribed. Witnesses, participants, and counsel have 30 days from the time the transcript becomes available to propose corrections in the transcript of oral testimony. Corrections are permitted only for transcription errors. The presiding officer shall promptly order justified corrections. Transcripts may be obtained following the hearing from the Division of Dockets Management at a cost not to exceed the actual cost of duplication.

(b) The transcript of testimony, exhibits, and other evidence admitted at the hearing and all papers and requests filed in the proceeding constitute the administrative record for the decision by the presiding officer and the entity designated by the Commissioner of Food and Drugs to decide the appeal, currently the DAB.

(c) The administrative record may be inspected and copied (upon payment of a reasonable fee) by anyone unless otherwise ordered by the presiding officer, who shall upon motion of any party

order otherwise when necessary to protect trade secrets or confidential commercial information, as defined in §20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under part 20.

§ 17.43 Posthearing briefs.

Any party may file a posthearing brief. The presiding officer shall fix the time for filing such briefs (which shall be filed simultaneously), which shall not exceed 60 days from the date the parties received the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The presiding officer may permit the parties to file responsive briefs. No brief may exceed 30 pages (exclusive of proposed findings and conclusions) unless the presiding officer has previously found that the issues in the proceeding are so complex, or the administrative record is so voluminous, as to justify longer briefs, in which case the presiding officer may set a longer page limit. Proposed findings of fact and conclusions of law shall not exceed 30 pages unless the presiding officer has previously found that the issues in the proceeding are so complex, or the administrative record is so voluminous, as to justify longer proposed findings and conclusions, in which case the presiding officer may set a longer page limit.

§ 17.45 Initial decision.

(a) The presiding officer shall issue an initial decision based only on the administrative record. The decision shall contain findings of fact, conclusions of law, and the amount of any penalties and assessments imposed.

(b) The findings of fact shall include a finding on each of the following issues:

(1) Whether the allegations in the complaint are true, and, if so, whether respondent's actions identified in the complaint violated the law;

(2) Whether any affirmative defenses are meritorious; and

(3) If the respondent is liable for penalties or assessments, the appropriate

amount of any such penalties or assessments, considering any mitigating or aggravating factors that he or she finds in the case.

(c) The presiding officer shall serve the initial decision or the decision granting summary decision on all parties within 90 days after the time for submission of posthearing briefs and responsive briefs (if permitted) has expired. If the presiding officer believes that he or she cannot meet the 90-day deadline, he or she shall notify the Commissioner of Food and Drugs or other entity designated by the Commissioner to decide the appeal of the reason(s) therefor, and the Commissioner or that entity may then set a new deadline.

(d) Unless the initial decision or the decision granting summary decision of the presiding officer is timely appealed, the initial decision or the decision granting summary decision shall constitute the final decision of FDA and shall be final and binding on the parties 30 days after it is issued by the presiding officer.

§ 17.47 Appeals.

(a) Either the Center or any respondent may appeal an initial decision, including a decision not to withdraw a default judgment, or a decision granting summary decision to the Commissioner of Food and Drugs or other entity the Commissioner designates to decide the appeal. The Commissioner has currently designated the Departmental Appeals Board (DAB) to decide appeals under this part. Parties may appeal to the DAB by filing a notice of appeal with the DAB, Appellate Division MS6127, Departmental Appeals Board, United States Department of Health and Human Services, 330 Independence Ave. SW., Cohen Bldg., rm. G-644, Washington, DC 20201, and the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, in accordance with this section.

(b)(1) A notice of appeal may be filed at any time within 30 days after the presiding officer issues an initial decision or decision granting summary decision.

(2) The Commissioner or the entity designated by the Commissioner to